



1648

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): LEMON et al. ) Group Art Unit: 1648  
Serial No.: 10/580,979 ) Examiner: Unknown  
Confirmation No.: 9290 ) Docket No. 265.00410101  
Filed: 31 May 2006 )

For: REPLICATION COMPETENT HEPATITIS C VIRUS AND METHODS OF USE

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

X An itemized return postcard.  
X An Information Disclosure Statement (2 pgs); copies of 0 applications; 1449 forms (14 pgs); and copies of 120 documents cited on the 1449 forms.

\_\_\_ Amendment \_\_\_ No Additional fee is required. \_\_\_ The fee has been calculated as shown:

Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x \$50 =	
Independent Claims				x \$200 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add \$360 Here →					
Total Additional Claim Fees Required					

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

**CERTIFICATE UNDER 37 C.F.R. §1.8:** The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8 day of November, 2006.

**MUETING, RAASCH & GEBHARDT, P.A.**  
Customer Number: 26813

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(LARGE ENTITY TRANSMITTAL UNDER RULE 1.8)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /B.L./



PATENT  
Docket No. 265.00410101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	LEMON et al.	)	Group Art Unit:	1648
		)		
Serial No.:	10/580,979	)	Examiner:	Unknown
Confirmation No.:	9290	)		
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For: REPLICATION COMPETENT HEPATITIS C VIRUS AND METHODS OF USE

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Pursuant to MPEP § 609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 form(s) is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Applicants also wish to bring the Examiner's attention to any pending U.S. Application cited in the 1449 form(s) submitted herewith, as well as any documents, Office Actions that may include rejections of similar claims, and any provisional U.S. patent applications referenced in the pending U.S. applications or in their file wrappers.

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**Information Disclosure Statement**

Page 2 of 2

Applicant(s): LEMON et al.

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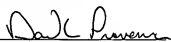
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It is believed that no fee is due, as this Information Disclosure Statement is filed prior to the receipt of any Action on the merits. However, in the event a fee is due, please charge any fee or credit any overpayment to Account No. 13-4895.

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number, if they can be of any assistance during prosecution of the present application.

**CERTIFICATE UNDER 37 C.F.R. 1.8:**

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8 day of November, 2006.



David L. Provence

November 8, 2006  
Date

Respectfully submitted

By

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<b>INFORMATION DISCLOSURE STATEMENT</b>	Atty. Docket No.: 265.00410101	Serial No.: 10/580,979
	Applicant(s): Lemon et al.	Confirmation. No.: 9290
	Application Filing Date: May 31, 2006	Group: 1648
	Information Disclosure Statement mailed: November 8, 2006	

**U.S. PATENT DOCUMENTS**

Examiner Initial	Copies Enclosed	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		5,766,906	06/16/98	Lemon et al.			
		5,846,767	12/08/98	Halpin et al.			
		5,912,167	06/15/99	Palmenberg et al.			
		6,127,116	10/03/00	Rice et al.			
		6,630,343	10/07/03	Bartenschlager			
		6,689,559	02/10/04	Wimmer et al.			
		6,921,634	07/26/05	Lemon et al.			
		6,930,095	08/16/05	Bichko			
		2002/0098202	07/25/02	Wimmer et al.			
		2002/0155582	10/24/02	Lemon et al.			
		2003/0073080	04/17/03	Rice et al.			
		2005/0153281	07/14/05	Lemon et al.			
		60/525,989		Lemon et al.			12/01/03

**FOREIGN PATENT DOCUMENTS**

Examiner Initial	Copies Enclosed	Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	X	WO 00/14263	03/16/00	PCT				
	X	WO 05/053516	06/16/05	PCT				

**OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)**

Examiner Initial	Copies Enclosed	Document Description
	X	Ausubel et al., eds., <i>Current Protocols in Molecular Biology</i> , Vol. 1-4, John Wiley & Sons, U.S.; title page, publication page and table of contents only, 12 pgs. (1994).

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Examiner Initial	Copies Enclosed	Document Description
	X	Bartenschlager et al., "Replication of Hepatitis C Virus," <i>J. Gen. Virol.</i> , July 2000; 81(7): 1631-1648.
	X	Bartosch et al., "Infectious Hepatitis C Virus Pseudo-particles Containing Functional E1-E2 Envelope Protein Complexes," <i>J Exp Med</i> , 3 March 2003;197(5):633-642.
	X	Beard et al., "An Infectious Molecular Clone of a Japanese Genotype 1b Hepatitis C Virus," <i>Hepatology</i> , 1999 July; 30(1):316-324.
	X	Berger et al., "Secreted Placental Alkaline Phosphatase: A Powerful New Quantitative Indicator of Gene Expression in Eukaryotic Cells," <i>Gene</i> , 1988 June 15; 66(1):1-10.
	X	Bieniasz et al., "Highly Divergent Lentiviral Tat Proteins Activate Viral Gene Expression by a Common Mechanism," <i>Mol. Cell. Biol.</i> , 1999 July; 19(7):4592-9.
	X	"BLAST," National Institutes of Health, Bethesda, MD [online]. Retrieved from Internet on April 17, 2001. <URL: <a href="http://www.ncbi.nlm.nih.gov/gorf/bl2.html">http://www.ncbi.nlm.nih.gov/gorf/bl2.html</a> >, 2 pgs.
	X	Blight et al., "Efficient Initiation of HCV RNA Replication in Cell Culture," <i>Science</i> , 2000 Dec 8; 290(5498):1972-1975.
	X	Blight et al., "Highly Permissive Cell Lines for Subgenomic and Genomic Hepatitis C Virus RNA Replication," <i>J. Virol.</i> , December 2002; 76(24):13001-13014.
	X	Blight et al., "Efficient Replication of Hepatitis C Virus Genotype 1a RNAs in Cell Culture," <i>J. Virol.</i> , March 2003; 77(5):3181-3190.
	X	Bukh et al., "Sequence analysis of the 5' noncoding region of hepatitis C virus," <i>Proc. Nat. Acad. Sci. USA</i> , June 1992;89: 4942-46.
	X	Bukh et al., "Mutations that Permit Efficient Replication of Hepatitis C Virus RNA in Huh-7 Cells Prevent Productive Replication in Chimpanzees," <i>Proc. Natl. Acad. Sci. USA</i> , 2002 Oct. 29; 99(22):14416-14421.

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	X	Cai et al., "Robust Production of Infectious Hepatitis C Virus (HCV) from Stably HCV cDNA-Transfected Human Hepatoma Cells," <i>Journal of Virology</i> , 2005 November, 79(22):13963-13973.
	X	Choo et al., "Genetic Organization and Diversity of the Hepatitis C Virus," <i>Proc. Natl. Acad. Sci. USA</i> , 1991 March; 88(6):2451-2455.
	X	Cullen, "Trans-activation of Human Immunodeficiency Virus Occurs via a Bimodal Mechanism," <i>Cell</i> . 1986 September 26;46(7):973-82.
	X	Cullen, Bryan R., "HIV-1 Auxiliary Proteins: Making Connections in a Dying Cell," <i>Cell</i> , 29 May 1998; 93:685-92.
	X	Date et al., "Genotype 2a Hepatitis C Virus Subgenomic Replicon Can Replicate in HepG2 and IMY-N9 Cells," <i>J. Biol. Chem.</i> , 2004 May 21; 279(21):22371-22376.
	X	Duhamel et al., "Secondary structure content of the HDV ribozyme in 95% formamide," <i>Nucleic Acids Research</i> , 1996;24(20):3911-3917.
	X	Enomoto et al., "There are Two Major Types of Hepatitis C Virus in Japan," <i>Biochem. Biophys. Res. Commun.</i> , 1990 August 16; 170(3):1021-1025.
	X	Evans et al., "Phosphorylation of hepatitis C virus nonstructural protein 5A modulates its protein interactions and viral RNA replication," <i>PNAS</i> , 31 August 2004;101(35):13038-13043.
	X	Forns et al., "Hepatitis C Virus Lacking the Hypervariable Region 1 of the Second Envelope Protein Is Infectious and Causes Acute Resolving or Persistent Infection in Chimpanzees," <i>PNAS</i> , 2000 Nov 21; 97(24):13318-23.
	X	Foy et al., "Regulation of Interferon Regulatory Factor-3 by the Hepatitis C Virus Serine Protease," <i>Science</i> , 2003 May 16; 300(5622):1145-1148.
	X	Foy et al., "Control of antiviral defenses through hepatitis C virus disruption of retinoic acid-inducible gene-1 signaling," <i>PNAS</i> , 22 February 2005;102(8):2986-2991.

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	X	Frese et al., "Interferon- $\alpha$ inhibits hepatitis C virus subgenomic RNA replication by an MxA-independent pathway," <i>J. Gen. Virol.</i> , 2001 Apr; 82(pt.4):723-33.
	X	Fried et al., "Peginterferon Alfa-2a Plus Ribavirin for Chronic Hepatitis C Virus Infection," <i>N. Engl. J. Med.</i> , 2002 September 26; 347(13):975-982.
	X	Fujisawa et al., "The Indirect Association of Human T-cell Leukemia Virus <i>tax</i> Protein with DNA Results in Transcriptional Activation," <i>J. Virol.</i> , 1991 August; 65(8):4525-4528.
	X	Gale et al., "Repression of the PKR Protein Kinase by the Hepatitis C Virus NS5A Protein: a Potential Mechanism of Interferon Resistance," <i>Clin. Diagn. Virol.</i> , 1998 July; 10(2-3):157-162.
	X	Gale et al., "Evidence that hepatitis C virus resistance to Interferon is mediated through repression of the PKR protein kinase by the nonstructural 5A protein," <i>Virology</i> , 1997;230:217-227.
	X	Graham et al., "A genotype 2b NS5B polymerase with novel substitutions supports replication of a chimeric HCV 1b:2b replicon containing a genotype 1b NS3-5A background," <i>Antiviral Research</i> , January 2006; 69(1):24-30.
	X	Grobler et al., "Identification of a Key Determinant of Hepatitis C Virus Cell Culture Adaptation in Domain II of NS3 Helicase," <i>J. Biol. Chem.</i> , 9 May 2003; 278(19):16741-16746.
	X	Gu et al., "Replication Studies Using Genotype 1a Subgenomic Hepatitis C Virus Replicons," <i>J. Virol.</i> , May 2003; 77(9):5352-5359.
	X	Guo et al., "Identification of a Novel RNA Species in Cell Lines Expressing HCV Subgenomic Replicons," Abstract P045, 7th International Meeting on Hepatitis C Virus and Related Viruses (Molecular Virology and Pathogenesis), The Marriott Resort Hotel, Gold Coast, Queensland, Australia, December 3-7, 2000; 1 pg.
	X	Guo et al., "Effect of Alpha Interferon on the Hepatitis C Virus Replicon," <i>J. Virol.</i> , September 2001; 75(18):8516-8523.

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	X	Hadzopoulou-Cladaras et al., "The <i>rev</i> ( <i>tr</i> s/ <i>art</i> ) Protein of Human Immunodeficiency Virus Type 1 Affects Viral mRNA and Protein Expression via a <i>cis</i> -acting Sequence in the <i>env</i> Region," <i>J. Virol.</i> , 1989 March; 63(3): 1265-1274.
	X	Harlow et al., <i>Antibodies: A Laboratory Manual</i> , Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY; title page, publisher's page, and table of contents, 9 pages (1988).
	X	Hayashi et al., "Molecular cloning and heterogeneity of the human hepatitis C virus (HCV) genome," <i>J. Hepatol.</i> , 1993;17 (Suppl. 3): S94-S107.
	X	Heller et al., "An in vitro model of hepatitis C virion production," <i>PNAS</i> , 15 February 2005;102(7):2579-2583. Published online 8 February 2005.
	X	Honda et al., "Stability of a stem-loop involving the initiator AUG controls the efficiency of internal initiation of translation of hepatitis C virus RNA," <i>RNA</i> , 1996;2: 955-68.
	X	Hsu et al., "Hepatitis C virus glycoproteins mediate pH-dependent cell entry of pseudotyped retroviral particles," <i>PNAS</i> , 10 June 2003;100(12): 7271-7276.
	X	Ikeda et al., "Human Hepatocyte Clonal Cell Lines that Support Persistent Replication of Hepatitis C Virus," <i>Virus Res.</i> , 1998 Aug.; 56(2):157-167.
	X	Ikeda et al., "Selectable Subgenomic and Genome-Length Dicistronic RNAs Derived from an Infectious Molecular Clone of the HCV-N Strain of Hepatitis C Virus Replicate Efficiently in Cultured Huh7 Cells," <i>J. Virol.</i> , Mar. 2002;76(6): 2997-3006.
	X	Inchauspe et al., "Genomic Structure of the Human Prototype Strain H of Hepatitis C Virus: Comparison with American and Japanese Isolates," <i>Proc. Natl. Acad. Sci. USA</i> , 1991 November15; 88(22):10292-10296.
	X	Kanda et al., "Generation of Infectious Hepatitis C Virus in Immortalized Human Hepatocytes," <i>Journal of Virology</i> , 2006 May; 80(9):4633-4639.
	X	Kato et al., "Replication of hepatitis C virus in cultured non-neoplastic human hepatocytes," <i>Jpn. J. Cancer Research</i> , August 1996;87:787-792.

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	X	Kato et al., "Susceptibility of Human T-Lymphotropic Virus Type I Infected Cell Line MT-2 to Hepatitis C Virus Infection," <i>Biochem. Biophys. Res. Commun.</i> , 1995 Jan.; 206(3):863-869.
	X	Kato et al., "Efficient Replication of the Genotype 2a Hepatitis C Virus Subgenomic Replicon," <i>Gastroenterology</i> , 2003 Dec.; 125(6):1808-1817.
	X	Kato, "Molecular Virology of Hepatitis C Virus," <i>Acta Medica Okayama</i> , 2001;55(3):133-159.
	X	Kim et al., "Domains I and II in the 5' Nontranslated Region of the HCV Genome Are Required for RNA Replication," <i>Biochem. Biophys. Res. Comm.</i> , 2002; 290: 105-112.
	X	Knowles et al., "Human hepatocellular carcinoma cell lines secrete the major plasma proteins and hepatitis B surface antigen," <i>Science</i> , July 1980;209(25):497-499.
	X	Kolykhalov et al., "Identification of a Highly Conserved Sequence Element at the 3' Terminus of Hepatitis C Virus Genome RNA," <i>J. Virol.</i> , 1996 June; 70(6):3363-71.
	X	Kolykhalov et al., "Hepatitis C Virus-Encoded Enzymatic Activities and Conserved RNA Elements in the 3' Nontranslated Region Are Essential for Virus Replication In Vivo," <i>J. Virol.</i> , 2000 February; 74(4):2046-2051.
	X	Krieger et al., "Enhancement of Hepatitis C Virus RNA Replication by Cell Culture-Adaptive Mutations," <i>J. Virol.</i> , May 2001; 75:4614-4624.
	X	Lai et al., "Generation and Characterization of a Hepatitis C Virus NS3 Protease-Dependent Bovine Viral Diarrhea Virus," <i>J. Virol.</i> , 2000 July; 74(14):6339-6347.
	X	Lanford et al., "Lack of Detection of Negative-Strand Hepatitis C Virus RNA in Peripheral Blood Mononuclear Cells and Other Extrahepatic Tissues by the Highly Strand-specific rTth Reverse Transcriptase PCR," <i>J. Virol.</i> , 1995 December; 69(12):8079-8083.

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	X	Lanford et al., "Anti-viral Effect and Virus-Host Interactions in Response to Alpha Interferon, Gamma Interferon, Poly(I)-Poly(C), Tumor Necrosis Factor Alpha, and Ribavirin in Hepatitis C Virus Subgenomic Replicons," <i>J. Virol.</i> , 2003 January., 77(2):1092-1104.
	X	Le Pogam et al., "Comparison of DNA Enzyme Immunoassay and Line Probe Assays (Inno-LiPA HCV I and II) for Hepatitis C Virus Genotyping," <i>J. Clin. Microbiol.</i> , 1998 May; 36(5):1461-1463.
	X	Lemon, "Selection of Cell Culture-adapted Hepatitis C RNA," Grant Abstract for Grant No. 2U19A140035-050001 [online]. National Institute of Allergy and Infectious Diseases, National Institutes of Health; project dates 01-AUG-96 to 31-JUL-05. Retrieved from the Internet on April 17, 2001; URL: < <a href="http://commons.cit.nih.gov/crisp/crisp_lib.getdoc?textkey=6340699&amp;p_query=&amp;ticket=1907498&amp;p_audit_session_id=4197699&amp;p_keywords=&gt;">http://commons.cit.nih.gov/crisp/crisp_lib.getdoc?textkey=6340699&amp;p_query=&amp;ticket=1907498&amp;p_audit_session_id=4197699&amp;p_keywords=&gt;</a> >, 2 pages.
	X	Lemon, "The Southeastern Cooperative Hepatitis C Research Group," Grant Abstract for Grant No. 2U19A140035-05 [online]. National Institute of Allergy and Infectious Diseases, National Institutes of Health; project dates 01-Aug-96 to 31-Jul-05. Retrieved from the Internet on April 17, 2001; URL: < <a href="http://commons.cit.nih.gov/crisp/crisp_lib.getdoc?textkey=6199426&amp;p_query=&amp;ticket=1907498&amp;p_audit_session_id=4197699&amp;p_keywords=&gt;">http://commons.cit.nih.gov/crisp/crisp_lib.getdoc?textkey=6199426&amp;p_query=&amp;ticket=1907498&amp;p_audit_session_id=4197699&amp;p_keywords=&gt;</a> >, 2 pages.
	X	Li et al., "Cellular response to conditional expression of Hepatitis C virus core protein in Huh7 cultured human hepatoma cells," <i>Hepatology</i> , May 2002;35(5): 1237-1246.
	X	Li et al., "Immune evasion by hepatitis C virus NS3/4A protease-mediated cleavage of the Toll-like receptor 3 adaptor protein TRIF," <i>PNAS</i> , 22 February 2005;102(8):2992-2997.
	X	Lohmann et al. "Replication of Subgenomic Hepatitis C Virus RNAs in a Hepatoma Cell Line," <i>Science</i> , 1999 July 2; 285(5424):110-113.
	X	Lohmann et al., "Adaptation of Selectable HCV Replicon to a Human Hepatoma Cell Line," Abstract P038, 7th International Meeting on Hepatitis C Virus and Related Viruses (Molecular Virology and Pathogenesis), The Marriott Resort Hotel, Gold Coast, Queensland, Australia, December 3-7, 2000; 1 pg.

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	X	Lohmann et al. "Mutations in Hepatitis C Virus RNAs Conferring Cell Culture Adaptation," <i>J. Virol.</i> 2001 February; 75(3):1437-49.
	X	Lohmann et al., "Viral and Cellular Determinants of Hepatitis C Virus RNA Replication in Cell Culture," <i>J. Virol.</i> , 2003 March., 77(5):3007-3019.
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